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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,284	07/01/2004	Gunvor Ekman-Ordeberg	1291-0215PUS1	9113

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EXAMINER	
MAIER, LEIGH C	
ART UNIT	PAPER NUMBER
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,284	EKMAN-ORDEBERG ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellison et al (Br. J. Obst. Gyn., 2001).

Ellison discloses the administration of a LMWH, enoxaparin, to a pregnant woman in combination with oxytocin. See page 757. It is noted that anticoagulant activity is not generally reported in the terms recited in the instant claims. However, enoxaparin appears to be the same type of heparin entity contemplated in the specification and would appear to meet this functional limitation. Likewise for the sulfate/hexosamine ratio recited in claim 7. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

It is noted that the reference is silent regarding any effect on the cervix. However, the step of the method requires only administering the active agent to a pregnant woman. Ellison discloses such administration, thereby inherently accomplishing the method.

Claims 1-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Greinacher et al (Br. J. Obst. Gyn., 2001).

Greinacher discloses the administration of Org 10172 (a combination of heparan sulfate, chondroitin sulfate and dermatan sulfate, or danaparoid) to a pregnant woman. See entire reference. See also discussion above regarding inherent properties.

It is noted that the reference is silent regarding any effect on the cervix. However, the step of the method requires only administering the active agent to a pregnant woman. Greinacher discloses such administration, thereby inherently accomplishing the method.

Claims 1, 5-7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanson et al (Thromb. Haem., 1999).

Sanson discloses a compilation of the use of a variety of LMWHs during pregnancy. See Table 1. It is noted that one of the LMWHs that is administered is dalteparin (Fragmin®), one of the agents disclosed in the instant specification. See Test 3 in the specification. See discussion above regarding inherent properties.

It is noted that the reference is silent regarding any effect on the cervix. However, the step of the method requires only administering the active agent to a pregnant woman. Sanson discloses such administration, thereby inherently accomplishing the method.

Claims 1-7, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ginsberg et al (Chest, 2001).

Ginsberg teaches the use of antithrombotics, including LMWHs and heparinoids, such as danaparoid, during pregnancy. See entire reference, particularly page 124S and recommendations at page 128S. It is noted that one of the LMWHs that is administered is dalteparin (Fragmin®), one of the agents disclosed in the instant specification. See Test 3. See discussion above regarding inherent properties.

It is noted that the reference is silent regarding any effect on the cervix. However, the step of the method requires only administering the active agent to a pregnant woman. Ginsberg discloses such administration, thereby inherently accomplishing the method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanson et al (Thromb. Haem., 1999) in view of Einarsson (US 5,714,477).

Sanson teaches as set forth above. The reference further discusses the use of antithrombotic therapy during pregnancy for a variety of disorders. See 1st paragraph of the introduction. The reference is silent regarding topical application.

Einarsson teaches a formulation for the transdermal administration of heparin or heparin fragments, with Fragmin® being exemplified. See col 1-2 and examples. The reference suggests this formulation for the treatment of disorders known to be treated by heparin or fragments. See paragraph bridging col 3-4.

It would have been obvious to one having ordinary skill in the art at the time the invention was known to administer a LMWH topically to a pregnant woman in need of antithrombotic therapy for the disorders outlined by Sanson. One of ordinary skill would be motivated to administer the LMWH in this manner for the convenience of the patient in avoiding daily injections. It is noted that the references are silent regarding any effect on the cervix. However, in carrying out the procedure as described by the combination of references, one of ordinary skill would be treating the same patient population required in the claim and would thereby accomplish the method. The fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for

patentability when the differences would otherwise be obvious. Ex parte Obiaya, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Claims 1-7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsberg et al (Chest, 2001) in view of Einarsson (US 5,714,477).

Ginsberg teaches as set forth above. The reference is silent regarding topical application.

Einarsson teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was known to administer a LMWH topically to a pregnant woman in need of antithrombotic therapy for the disorders outlined by Ginsberg. One of ordinary skill would be motivated to administer the LMWH in this manner for the convenience of the patient in avoiding daily injections. It is noted that the references are silent regarding any effect on the cervix. Please see discussion above.

Claims 1, 5-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanson et al (Thromb. Haem., 1999) in view of Ellison et al (Br. J. Obst. Gyn., 2001).

Sanson teaches as set forth above. The reference is silent regarding the administration of a LMWH in combination with oxytocin.

Ellison teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was known to administer a LMWH in combination with oxytocin to a pregnant woman in need of antithrombotic therapy and further in need of labor induction. One of ordinary skill

would be motivated to administer the LMWH in combination with oxytocin for the additive effects. The use of oxytocin for labor induction is well known in the art, and Ellison has demonstrated its utility in combination with LMWH. Again, the patient population that would be treated as suggested by the combination of references is fully encompassed by the population contemplated in the instant claims, and in following the suggestions of the art, one of ordinary skill would accomplish the method.

Claims 1-8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsberg et al (Chest, 2001) in view of Ellison et al (Br. J. Obst. Gyn., 2001).

Ginsberg teaches as set forth above. The reference is silent regarding the administration of a LMWH in combination with oxytocin.

Ellison teaches as set forth above.

It would have been obvious to one having ordinary skill in the art at the time the invention was known to administer a LMWH or heparinoid in combination with oxytocin to a pregnant woman in need of antithrombotic therapy and further in need of labor induction. One of ordinary skill would be motivated to administer the LMWH or heparinoid in combination with oxytocin for the additive effects. The use of oxytocin for labor induction is well known in the art, and Ellison has demonstrated its utility in combination with antithrombotic therapy. Again, the patient population that would be treated as suggested by the combination of references is fully encompassed by the population contemplated in the instant claims, and in following the suggestions of the art, one of ordinary skill would accomplish the method.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laster (EP 1016410) in view of Einarsson (US 5,714,477)—claim 9 or Atad (US 4,976,692)—claim 8.

Laster teaches the administration of glycosaminoglycans, preferably LMW heparin, heparan or dermatan, for the treatment of pre-eclampsia. See, for example, paragraph [0042]. The reference does not exemplify the treatment of women. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to administer these products to treat pre-eclampsia with a reasonable expectation of success because it is suggested in the art.

Laster does not teach topical administration or the administration of glycosaminoglycans in combination with oxytocin.

Einarsson teaches as set forth above.

It is known that pre-eclampsia is one of the most common indication for labor induction, which it typically done by the administration of oxytocin. See Atad at page 5, lines 50-58.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to administer glycosaminoglycans as set forth above. It would be further obvious to administer the agents topically as taught by Einarsson for the advantages set forth above, with a reasonable expectation of success. It would be further obvious to administer the agents in combination with oxytocin because the need for labor induction is common in women with pre-eclampsia.

Again, the patient population that would be treated as suggested by the combination of references is fully encompassed by the population contemplated in the instant claims, and in following the suggestions of the art, one of ordinary skill would accomplish the method.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
December 6, 2006